

SEVERE DAYTIME COLD AND FLU DAYTIME MAXIMUM STRENGTH NON-DROWSY SEVERE- acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled Walgreens

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DAYTIME NON-DROWSY MAXIMUM STRENGTH SEVERE COLD & FLU

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hours

adults & children 12 years & over	2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

Other information

- store at room temperature

Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

Call toll free: 1-888-333-9792

PRINCIPAL DISPLAY PANEL

Walgreens

Compare to Vicks® DayQuil® Severe

Cold&Flue active ingredients††

DAYTIME NON-DROWSY

Severe Cold & Flu

ACETAMINOPHEN/ACHES/ FEVER/ SORE THROAT

DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT

GUAIFENESIN/ EXPECTORANT

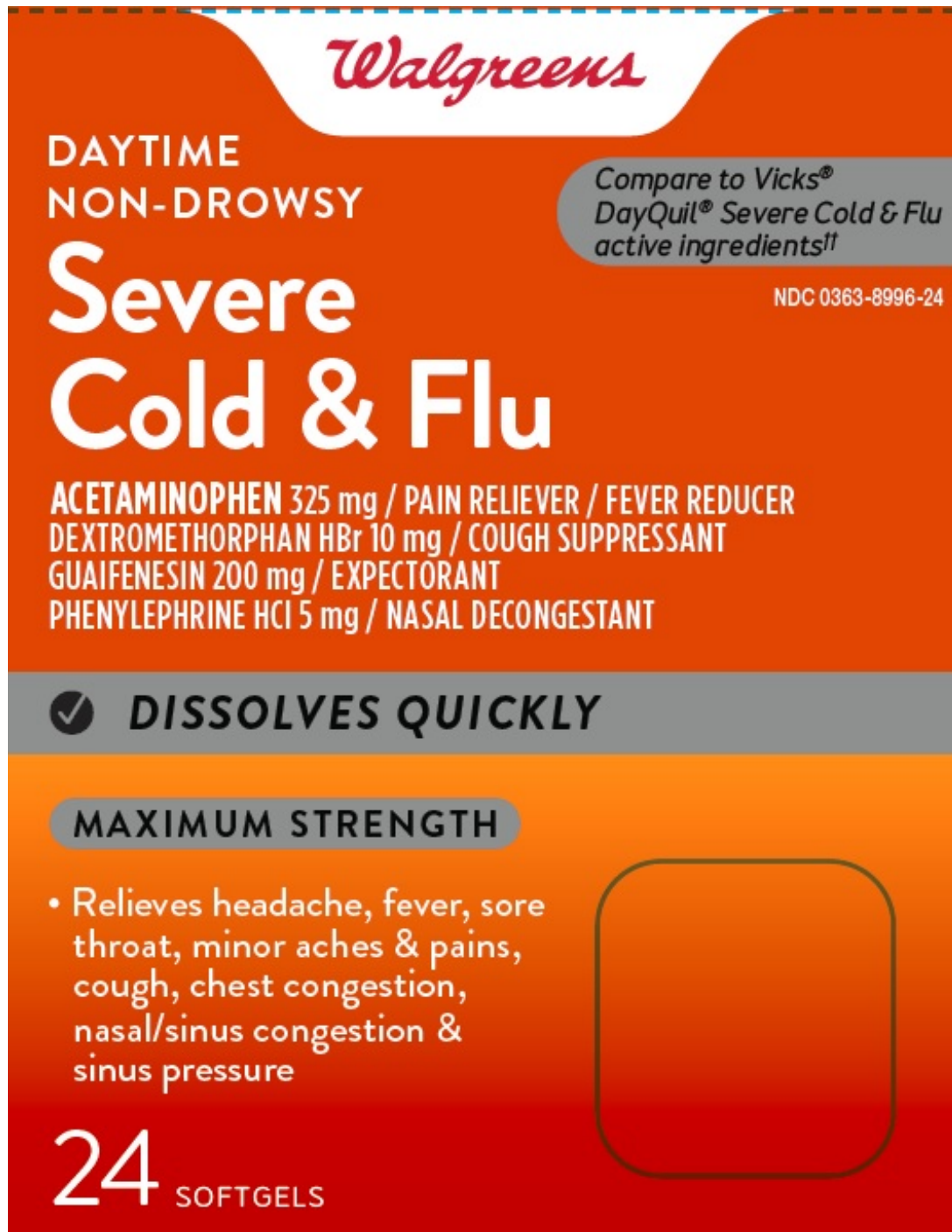
PHENYLEPHRINE HCL/NASAL DECONGESTANT

MAXIMUM STRENGTH

Relieves headache, fever, sore throat,
minor aches & pains, cough, chest congestion,
nasal/sinus congestion & sinus pressure

24

SOFTGELS



The image shows the front of a Walgreens Severe Cold & Flu Daytime Non-Drowsy Softgels box. The box is primarily orange and red. At the top, the Walgreens logo is in white script on a red background. Below the logo, the text "DAYTIME NON-DROWSY" is in white, followed by "Severe Cold & Flu" in large white letters. To the right, a grey banner says "Compare to Vicks® DayQuil® Severe Cold & Flu active ingredients†". Below this, the NDC number "NDC 0363-8996-24" is printed. The active ingredients are listed in white: "ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER", "DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT", "GUAIFENESIN 200 mg / EXPECTORANT", and "PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT". A grey banner with a checkmark icon says "DISSOLVES QUICKLY". Below this, a grey banner says "MAXIMUM STRENGTH". A list of symptoms is shown in white: "• Relieves headache, fever, sore throat, minor aches & pains, cough, chest congestion, nasal/sinus congestion & sinus pressure". At the bottom left, "24" is in large white letters, with "SOFTGELS" in smaller white letters. A large, empty, rounded square is on the right side of the box.

Walgreens

DAYTIME
NON-DROWSY

**Severe
Cold & Flu**

Compare to Vicks®
DayQuil® Severe Cold & Flu
active ingredients†

NDC 0363-8996-24

ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT
GUAIFENESIN 200 mg / EXPECTORANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

✓ **DISSOLVES QUICKLY**

MAXIMUM STRENGTH

- Relieves headache, fever, sore throat, minor aches & pains, cough, chest congestion, nasal/sinus congestion & sinus pressure

24 SOFTGELS

**SEVERE DAYTIME COLD AND FLU DAYTIME MAXIMUM STRENGTH
NON-DROWSY SEVERE**

acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride
capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-8996
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL (OBLONG)	Size	20mm
Flavor		Imprint Code	341;908
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8996-24	2 in 1 CARTON	08/23/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - Walgreens (008965063)

Revised: 11/2021

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